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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/786,720

02/26/2004

Margot Mary O'Toole

WYE-030

2740

54623

7590

09/25/2007

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BOSTON, MA 02111-2950

EXAMINER

MYERS, CARLA J

ART UNIT

PAPER NUMBER

1634

MAIL DATE

DELIVERY MODE

09/25/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/786,720

Applicant(s)

O'TOOLE ET AL.

Examiner

Carla Myers

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application

6) ☒ Other: Sequence alignment

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on August 1, 2007 has been entered.

2. Claim 20 is pending. All previous grounds of rejection are withdrawn in view of the amendments to claim 20. However, this action contains a new grounds of rejection as set forth below.

New Grounds of Rejection

Claim Rejections - 35 USC § 112 – New Matter

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification as originally filed does not appear to provide support for the amendment to claim 20 to recite a method comprising the step of comparing the expression of "SFRP1 (SEQ ID NO: 15) mRNA" in kidney samples of a mouse before and after administration of an agent to determine if said agent modulates expression of SEQ ID NO: 15 in the mouse. As broadly written, the claims encompass methods in which a mRNA consisting of or comprising SEQ ID NO: 15 is detected in a mouse. However, upon further review of the specification, it appears that SEQ ID NO: 15 constitutes the human SFRP1 mRNA. The mouse SFRP1 mRNA shares only 26.8% identity with SEQ ID NO: 15 and thereby is substantially distinct from the human SFRP1 mRNA of SEQ ID NO: 15 (see the attached sequence alignment). The specification does not teach the concept of detecting the human mRNA of SEQ ID NO: 15 in mice having lupus. For example, the specification does not teach the generation of transgenic mice expressing SEQ ID NO: 15 and the analysis of expression of SEQ ID NO: 15 in such transgenic mice to determine if an agent effects the expression of SEQ ID NO: 15. The specification (e.g., para [0077]) does teach that the "discovery of the LRG expression patterns in SLE/LN-affected animals allows for the screening of agents that can modulates LRG expression or LRG activity. The agents may be screened by their effects on LRG expression at the mRNA or protein level, or by their effect on the activity of the LRG product. " However, the specification exemplifies only methods in which the expression levels of mouse mRNAs are analyzed in SLE-affected mice using an Affymetrix gene chip array (pages 65-66). Human orthologs of mouse genes differentially expressed in SLE-affected mice were identified using HomoloGene (page

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69). The specification (pages 18, 19, 21 and Table 1) indicates that the methods which detect lupus-related genes (LRGs) are intended to include the detection of mutants, isoforms and alternatively spliced variants of the LRGs. However, the specification does not appear to provide a sequence of the mouse SFRP1 mRNA that is overexpressed in SLE-affected mice. Accordingly, it does not appear that the specification as originally filed provides basis for the particular embodiment of a method of administering an agent to a mouse with lupus and comparing the expression of a mRNA comprising SEQ ID NO: 15 before and after said administration in order to determine if the agent modulates expression of SEQ ID NO: 15 in the mouse.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is 571-272-0747. The examiner can normally be reached on Monday-Thursday (6:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carla Myers/

Primary Examiner, Art Unit 1634

<!--StartFragment-->BC094662

LOCUS BC094662 4375 bp mRNA linear ROD 11-AUG-2006

DEFINITION Mus musculus secreted frizzled-related sequence protein 1, mRNA
(cDNA clone MGC:102081 IMAGE:30363219), complete cds.

ACCESSION BC094662

VERSION BC094662.1 GI:63102234

KEYWORDS MGC.

SOURCE Mus musculus (house mouse)

ORGANISM Mus musculus

Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
Mammalia; Eutheria; Euarchontoglires; Glires; Rodentia;
Sciurognathi; Muroidea; Muridae; Murinae; Mus.

REFERENCE 1 (bases 1 to 4375)

AUTHORS Strausberg,R.L., Feingold,E.A., Grouse,L.H., Derge,J.G.,
Klausner,R.D., Collins,F.S., Wagner,L., Shenmen,C.M., Schuler,G.D.,
Altschul,S.F., Zeeberg,B., Buetow,K.H., Schaefer,C.F., Bhat,N.K.,
Hopkins,R.F., Jordan,H., Moore,T., Max,S.I., Wang,J., Hsieh,F.,
Diatchenko,L., Marusina,K., Farmer,A.A., Rubin,G.M., Hong,L.,
Stapleton,M., Soares,M.B., Bonaldo,M.F., Casavant,T.L.,
Scheetz,T.E., Brownstein,M.J., Usdin,T.B., Toshiyuki,S.,
Carninci,P., Prange,C., Raha,S.S., Loquellano,N.A., Peters,G.J.,
Abramson,R.D., Mullahy,S.J., Bosak,S.A., McEwan,P.J.,
McKernan,K.J., Malek,J.A., Gunaratne,P.H., Richards,S.,
Worley,K.C., Hale,S., Garcia,A.M., Gay,L.J., Hulyk,S.W.,
Villalon,D.K., Muzny,D.M., Sodergren,E.J., Lu,X., Gibbs,R.A.,
Fahey,J., Helton,E., Kettelman,M., Madan,A., Rodrigues,S.,
Sanchez,A., Whiting,M., Madan,A., Young,A.C., Shevchenko,Y.,
Bouffard,G.G., Blakesley,R.W., Touchman,J.W., Green,E.D.,
Dickson,M.C., Rodriguez,A.C., Grimwood,J., Schmutz,J., Myers,R.M.,
Butterfield,Y.S., Krzywinski,M.I., Skalska,U., Smailus,D.E.,
Schnerch,A., Schein,J.E., Jones,S.J. and Marra,M.A.

CONSRTM Mammalian Gene Collection Program Team

TITLE Generation and initial analysis of more than 15,000 full-length
human and mouse cDNA sequences

JOURNAL Proc. Natl. Acad. Sci. U.S.A. 99 (26), 16899-16903 (2002)

PUBMED 12477932

REFERENCE 2 (bases 1 to 4375)

CONSRTM NIH MGC Project

TITLE Direct Submission

JOURNAL Submitted (06-MAY-2005) National Institutes of Health, Mammalian
Gene Collection (MGC), Bethesda, MD 20892-2590, USAREMARK NIH-MGC Project URL: <http://mgc.nci.nih.gov>

COMMENT Contact: MGC help desk

Email: cgapbs-r@mail.nih.gov

Tissue Procurement: Dr. Jim Lin, University of Iowa

cDNA Library Preparation: M. Bento Soares, University of Iowa

cDNA Library Arrayed by: The I.M.A.G.E. Consortium (LLNL)

DNA Sequencing by: Sequencing Group at the Stanford Human Genome

Center, Stanford University School of Medicine, Stanford, CA 94305

Web site: <http://www-shgc.stanford.edu>Contact: (Dickson, Mark) mcd@paxil.stanford.eduDickson, M., Schmutz, J., Grimwood, J., Rodriguez, A., and Myers,
R. M.Clone distribution: MGC clone distribution information can be found
through the I.M.A.G.E. Consortium/LLNL at: <http://image.llnl.gov>

Series: IRAK Plate: 195 Row: 1 Column: 16

This clone was selected for full length sequencing because it
passed the following selection criteria: matched mRNA gi: 7305480.

FEATURES Location/Qualifiers

source 1. .4375

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ORIGIN

Query Match 26.8%; Score 1196.8; DB 6; Length 4375;
 Best Local Similarity 62.0%; Pred. No. 0;
 Matches 2789; Conservative 0; Mismatches 1497; Indels 214; Gaps 48;

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Db      3966 CCCTGTAACCAGATGCTCTGTTGGACCTTCATAGCCGGACGTGGTTCA--AGATGTGCTC 4023

Qy      4123 GAGGAGAGCACCCCTAGGCAGCCTGCAGGGAATAACATACTGGCCGTTCTGACCTGTTGCC 4182
      || |||  ||||  ||  | |  | ||  |||  ||||  | ||||| |||  | |
Db      4024 CAGAAGCAGACCCGGGGTCACATCTCCAGGATGGCATGTTGGCTGCTCTGACCTGGCG-C 4082

Qy      4183 AGCAGATACACAGGACATGGATGAAATTCCTGTTTCTCTAGTTTCTTCTGCTAGTACTC 4242
      | | | | | || || || | ||||| |||  | || |||  | |||  |
Db      4083 TGTGGGTCCTAAGCGCAGAGACGGAATTCCTGTTGGCCCTGGTTCCCCCTCCTCGCACC 4142

Qy      4243 CTCT-----TTTAGATCCTAAGTCTCT--TACAAAAGCTTTGAATACTGTGAAA 4289
      | ||  ||||  | ||||| || |  ||||| ||||| ||||| |||||
Db      4143 CCCTGAGGACTCCACTTTTATAGCCTAAGCCTTTTATACAAAAGCTTTGAATACTGTGAAG 4202

Qy      4290 ATGTTTTACATTCCATTTTCAATTTGTGTTGTTTTTTTAACTGCATTTTACCAGATGTTTTG 4349
      ||||| ||||| || |||||  ||||  |||  ||||| ||||| ||||| |||||
Db      4203 ATGTTTTACATTCTTCTCATTCCTGTTG-TTCTTAACTACATTTGACCAGATGTTTTG 4261

Qy      4350 ATGTTATCGCTTATGTTAATAGTAATCCCGTACGTGTTTCATTTTATTTTCATGCTTTTT 4409
      ||||| |||  | ||||| ||||| |||||  |||  |||  ||||| |||||
Db      4262 ATGTTATCACGTATGTTAATAGTGATTCCCAGGTGTG----TTTGTTTTTCATGCTTTCC 4317

Qy      4410 CAGCCATGTATCAATATTCACCTGACTAAAATCACTCAATTAATCAATGAAAAAAAAAAAA 4469
      | ||||  ||||| ||||| ||||| ||||| || ||| ||  ||||| |||||
Db      4318 CTGCCA-----ATGTATTCACCTTCACTAAAATCACTCGATCAATAAAAAAAAAAAAAAA 4372
<!--EndFragment-->
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